

### **REMARKS**

Claims 1 and 48-50 have been amended to recite a pore able to bind to an analyte, where binding of the analyte to the pore alters a frequency of oscillation of the pore. Support for this amendment can be found throughout the specification, for example, on page 13, lines 1-26.

Claims 25, 27, 34, and 46 have been amendment to recite that the ion channel has a frequency of oscillation, where the frequency of oscillation of the ion channel is altered upon binding of the ion channel to an analyte. Support for this amendment can be found throughout the specification, and as one example, on page 14, lines 7-14.

Dependent claim 55 has been incorporated into independent claim 53, from which it depended. Accordingly, claim 55 has been canceled. Claim 53 has also been amended to recite that the subunit or derivative thereof is able to bind to an analyte. Support for this amendment can be found throughout the specification, for example, on page 10, lines 17-18.

No new matter has been added. Claims 1-54 are now pending for examination.

### **Rejection of Claims 27-33 under 35 U.S.C. §112, ¶2**

Claims 27-33 have been rejected under 35 U.S.C. §112, ¶2, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

With respect to claim 27, the Office Action suggests that the preamble should explicitly state what the method is drawn to, in order to comply with 35 U.S.C. §112, ¶2. Applicants are not aware of such a requirement. Applicants note that what is required under §112, ¶2 is that “those skilled in the art understand what is being claimed when the claims are read in light of the specification.” Orthokinetics v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1 U.S.P.Q.2d 1081 (Fed. Cir. 1986). Thus, what is required to comply with §112, ¶2 is that the recited elements in the body of the claim allow the meaning of the claim to be understood by those skilled in the art. Applicants believe that the body claim 27 fully explains the intended scope and meaning of the claim in language that would be clear and understandable to those of ordinary skill in the art. Applicants do not believe that a more extensive preamble is required to render the scope and meaning of the claims understandable to those skilled in the art, and for this reason, Applicants

thus believe that a more extensive preamble is not required to satisfy 35 U.S.C. §112, ¶2, and thus, Applicants respectfully request that the rejection of claim 27 be withdrawn.

The Office Action asserts that it is unclear what is meant by “steadily” in claim 28. Applicants note that the term “steadily for at least 1 day” is defined in the specification, for example, on page 13, lines 14-16. Accordingly, it is respectfully requested that the rejection be withdrawn.

The Office Action asserts that it is unclear what is meant by the term “stable” in claim 33. Applicants note that the term “stable” is defined in the specification, for example, on page 11, lines 4-5.

Claims 29-32 were also rejected under 35 U.S.C. §112, ¶2, but the Office Action has not set forth any reasons for the rejection of these claims. Accordingly, clarification or withdrawal of the rejection of claims 29-32 is respectfully requested.

Rejection of Claims 1-13, 15-21, 24-31, 33-35, and 46-52 under 35 U.S.C. §102(b)

Claims 1-13, 15-21, 24-31, 33-35, and 46-52 have been rejected under 35 U.S.C. §102(b) as being anticipated by Ikematsu, et al., U.S. Patent No. 5,503,744 (“Ikematsu”).

Applicants do not see where Ikematsu discloses or suggests an analyte that can bind to a pore or an ion channel, as recited in claims 1, 25, 27, 34, and 48-50 (as amended). Instead Ikematsu is directed towards the generation of oscillating currents, and, in some cases, such oscillation may be initiated using light (e.g., col. 7, lines 1-13). Accordingly, it is believed that independent claims 1, 25, 27, 34, 46, and 48-50 are patentable in view of Ikematsu, and it is respectfully requested that the rejection of these claims be withdrawn. Dependent claims 2-13, 15-21, 24, 26, 28-31, 33, 35, 47, and 51 are believed to be patentable for at least these reasons, and it is respectfully requested that the rejection of these claims also be withdrawn.

With respect to claim 52, it is not seen where in Ikematsu are two separate membranes positioned adjacent to at least one electrolyte reservoir disclosed or suggested. The Office Action suggests that the current monitored by Ikematsu “appears” to come from a plurality of different ion-channel containing membranes, but does not point to where in Ikematsu this does disclose. Fig. 2 in Ikematsu only illustrates one membrane, while column 7, lines 36-44 discloses an anion selective membrane and a cation and selective ion channel (or vice versa), but

does not disclose or suggest the use of more than one membrane. Accordingly, it is believed that claim 52 is patentable in view of Ikematsu, and it is respectfully requested that the rejection be withdrawn.

Rejection of Claims 25, 27-33, 36, 38-43, 45, and 46 under 35 U.S.C. §102(b) or §103(a)

Claims 25, 27-33, 36, 38-43, 45, and 46 have been rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being obvious over, McGeoch, et al., *Brain Research*, 766 (1997), pp. 188-194 ("McGeoch").

It is not seen where in McGeoch is an ion channel able to bind to an analyte disclosed or suggested. McGeoch is directed towards the study of subunit c of adenosine triphosphate (ATP) synthase, and is not directed towards the detection of external analytes. Accordingly, it is respectfully requested that the rejection of independent claims 25, 27, and 46, and dependent claims 28-33 be withdrawn.

With respect to independent claim 36 and dependent claims 38-43 and 45, it is not seen where in McGeoch is a sample allowed to bind to at least one ion channel. McGeoch does not disclose or suggest analyte binding. Instead, in McGeoch, Fig. 2 shows the behavior of reconstituted subunit c of ATP synthase at different voltages for different species (see, e.g., the caption of Fig. 2). Nowhere is it disclosed or suggested that current oscillations are altered upon binding of the subunit to a sample of an analyte, as recited in independent claim 36. Accordingly, it is believed that claims 36, 38-43, and 45 are patentable and not obvious in view of McGeoch for at least these reasons, and it is respectfully requested that the rejection of these claims be withdrawn.

Rejection of Claims 1, 2, 6-24, 26, 34, 35, 47, 49-51 and 53-55 under 35 U.S.C. §103(a)

Claims 1, 2, 6-24, 26, 34, 35, 47, 49-51 and 53-55 have been rejected under 35 U.S.C. §103(a) as being unpatentable over McGeoch in view of Alberts, et al., *Molecular Biology of the Cell*, Third Edition, 1994 ("Alberts").

The Patent Office has not pointed to a suggestion or a motivation in either McGeoch or Alberts to combine McGeoch with Alberts. The Office Action states "the use of conventional structure for the performance of specific experiments requires only routine skill in the art," but

the Office Action does not indicate what would be conventional in the art, nor does the Office Action point to a motivation in either McGeoch or Alberts to make the combination.

Further, even assuming that the combination was made (which Applicants do not concede), the combination of McGeoch and Alberts would not reach the invention as claimed in independent claims 1, 34, 49, 50 and 53. Nowhere in either McGeoch or Alberts is there a disclosure or suggestion that an ion channel pore can bind to an analyte. Accordingly, it is respectfully requested that the rejection of independent claims 1, 34, 49, and 50 be withdrawn. Dependent claims 2, 6-24, 26, 35, 51, 54, and 55 are believed to be patentable for at least reasons, and it is respectfully requested that the rejection of these claims also be withdrawn.

Dependent claim 47 depends from claim 46, which was not rejected as being unpatentable over McGeoch in view of Alberts. It is believed that claim 47 is patentable for at least the reasons explained above with respect to claim 46 in view of McGeoch, and it is respectfully requested that the rejection of claim 47 be withdrawn.

Rejection of Claims 14, 32, 53-55 (and Claims 10-13 and 31) under 35 U.S.C. §103(a)

Claims 14, 32, and 53-55 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Ikematsu in view of McGeoch. Further, claims 10-13 and 31 also appear to have been rejected on these grounds, although it is not clear why the Office Action states that these claims were rejected “in the alternative.” Clarification is respectfully requested.

The Patent Office has not pointed to a suggestion or a motivation in either McGeoch or Alberts to combine Ikematsu with McGeoch. The Office Action states that the combination would be made because the protein of McGeoch “has been identified as a viable candidate providing a large range of oscillating frequencies.” However, the Patent Office has not pointed to a disclosure or a suggestion in Ikematsu that a “large range of oscillating frequencies” is desired. Ikematsu, in fact, teaches away from using large ranges of oscillating frequencies in a device. Ikematsu is directed towards oscillating phenomenon that can be used as signals in a “bioinformation processing system and hence can be the base of a biocomputer” (col. 8, lines 3-5). Ikematsu also discloses the use of “predetermined fluctuating phenomenon” (col. 7, lines 9-13). Thus, it is believed that there is no motivation in Ikematsu for the use of a device having a

large range of oscillating frequencies, and thus, it is believed that the combination of Ikematsu with McGeoch is improper.

Further, even assuming that the combination was made (which Applicants do not concede), the combination of Ikematsu and McGeoch would not reach the invention as claimed. Nowhere in either Ikematsu and McGeoch is there a disclosure or suggestion that a pore or an ion channel can bind to an analyte. Thus, the combination of Ikematsu and McGeoch, to the extent these references could be combined, would not render obvious all of the limitations of claims 10-14, 31, 32, and 53-55. Accordingly, it is respectfully requested that the rejection of these claims be withdrawn.

#### Rejection of Claim 44 under 35 U.S.C. §103(a)

Claim 44 has been rejected under 35 U.S.C. §103(a) as being unpatentable over McGeoch in view of WO 97/05477. Claim 44 depends from claim 36. According to the Office Action, the basis for the rejection is that McGeoch teaches a method meeting all of the limitations of claim 36, except for the limitation added in claim 44 directed to derivatizing the ion channel with functional groups to detect a predetermined analyte. The Office Action goes on to assert that claim 44 discloses such a limitation, and that it would have therefore been obvious to combine McGeoch with WO 97/05477.

For at least the reasons explained above with respect to the rejection under §102(b) or §103(a) in view of McGeoch, the premise of the rejection under §103(a) (that McGeoch teaches all of the limitations other than derivatizing the ion channel with functional groups to detect a predetermined analyte, i.e., all of the limitations of claim 36) is believed to be incorrect. Accordingly, while Applicants do not concede that there would have been any motivation to combine McGeoch and WO 97/05477 in the manner suggested in the Office Action, the present rejection cannot stand, regardless. Thus, withdrawal of the rejection of claim 44 is respectfully requested.

#### CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner

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believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicants' representatives at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

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